# Medical Investment DA

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#### Uniqueness: Investment in medicine up now, but risk of losing patents creates uncertainty

Christel 24

Michael Christel is the group managing editor of Pharmaceutical Executive, Pharmaceutical Commerce, and Applied Clinical Trials. "The Twists and Turns in Biopharma Dealmaking: 2024 Trends." Published by PharmExec. Published on January 26, 2024. Available here: (https://www.pharmexec.com/view/twists-turns-biopharma-dealmaking-2024-trends) - AP

Spikes and valleys in M&A and dealmaking activity have been fairly routine and expected occurrences over the years in the biopharmaceutical sector. Just when they’ll strike, however, and the trajectories triggered as a result, are becoming less easy to pin down these days. That’s due in large part to a wildly evolving and complex operating environment for life sciences companies in projecting and ultimately executing on their product strategies, whether market- or development-focused. The argument could be made that would-be M&A participants today are tasked with navigating and acting on the most volatile mix of business drivers and influences—internally and on macro levels—in the industry’s history. As far as the headwinds involved, they include looming mass patent expirations for Big Pharma flagship medicines; the still-tenuous market and IPO climate for already cash-strapped biotechs, particularly early-stage, small-cap companies; and hope and caution around further interest-rate movement in the US. Hurdles are also emerging as a result of Inflation Reduction Act (IRA) legislation in the US and potential impacts from November elections; heightened M&A and dealmaking scrutiny by the Federal Trade Commission; and continued broader geopolitical and regulatory uncertainty. All these forces swirling together, experts agree, raise the urgency of sound decision-making—on dealmaking. And not just for the fates of the parties involved, but in benefiting the greater biopharma ecosystem and efforts to sustain the industry’s innovative lifeblood and future commercial viability.

#### Specifically, corporations see protection of TK as creating too much unpredictability

Reddy & Lakshmikumaran 15

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Among all of the polarizing debates on intellectual property (IP) regimes around the world today, the traditional knowledge (TK) debate has not received as much attention as the patentability of genes and diagnostics. Not only does the TK debate feature an interesting role reversal between developing and developed countries, it also raises fundamental questions about equity, property, and justice. In the TK debate, it is the developing countries that are traditionally the fiercest critics of an exclusionary IP regime and that are seeking to create new property rights in the domain of TK. These countries, like India, argue that indigenous communities should be entitled to the protection of their TK through a global treaty regime just as modern industrial IP is protected through treaties such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). On the other hand, the corporations of the developed world along with their governments, which have traditionally lobbied for greater IP rights through agreements like TRIPs, are possibly the greatest opponents of the demands made by developing countries because of fears that the proposed measures to protect TK would create an unpredictable regime that would kill innovation through trade barriers. Although there has been some consensus on this point in recent years between opposing lobbies, with jurisdictions like the European Union (EU) agreeing to side with the developing countries, a global treaty is still a distant dream despite more than a decade of global negotiations.

#### Retroactive patent reform harms innovation and break centuries of traditional policymaking – exacerbating investor timidness

Masur & Mortara 19

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This is particularly true for areas of law that are explicitly driven by judicial lawmaking. For instance, the Federal Circuit has described the rule that laws of nature, abstract ideas, and natural phenomena are not patentable subject matter as a “judicially-crafted exception[].”276 If the courts have the authority to craft such an exception—and they undoubtedly do—then they similarly have the authority to apply it only prospectively if they so choose.277 In addition, suppose that the Federal Circuit were to issue a decision in 2018 that changed a particular patent rule from Rule X to Rule Y. Even if the court were merely finding law, and even if this decision meant that Rule Y had always been correct, and Rule X had always been incorrect, this does not mean that the court would be obligated to apply Rule Y retroactively. Federal courts have the authority to tailor their remedies pragmatically.278 In such a case, the Federal Circuit could decide that even though the correct rule has always been Rule Y, it will not apply Rule Y to parties that have already applied for patents under Rule X. The pragmatic reason would be the reliance interests held by those parties, the same rationale that animates stare decisis and leads courts to adhere to potentially suboptimal rules over time.279 Thus, even courts or scholars who hold a formalistic view of Article III should not balk at the idea of nonretroactive patent decisions. What is more, there are good reasons to reject such a formalistic view of the judicial role. Ever since the legal realists, sophisticated legal observers have understood that the courts make law, just as legislatures and agencies do.280 The notion that the courts only “find” what law the other branches have made is a legal fiction that fools few educated observers and is routinely contravened in public by other judges.281 Perhaps it is politically expedient for courts to maintain that they do not make new law, but even if so, it is a strategy that is becoming less and less useful each day.282 More importantly, it lacks the virtue of being true. As a descriptive matter, this could well be why the Supreme Court has expressed concern about courts being granted unencumbered authority to issue prospective or retrospective decisions as they see fit.283 But as a normative matter, it does not offer grounds for doubting prospective judicial lawmaking.284 Indeed, the Ex Post Facto Clause of the Constitution effectively requires prospective judicial lawmaking with respect to substantive criminal law.285 The Ex Post Facto Clause is based upon the principle “that persons have a right to fair warning of that conduct which will give rise to criminal penalties” and thus cannot be convicted under a rule of law that did not exist at the time they engaged in the conduct in question.286 The Clause applies only to Congress, but the Court has extended and applied the same principle to judicial decisions via the Due Process Clause.287 This means that any judicial decision that broadens the scope of criminal liability—by limiting a constitutional protection, for instance—is necessarily prospective only, applying only to conduct that occurs after the Court’s decision is announced.288 This of course precisely parallels our proposed approach to patent law. And here, the legislative nature of purely prospective judicial rulings has not troubled the Court. The Court’s view of nonretroactive judicial decisionmaking is also incongruous with the law of habeas corpus. In the realm of habeas and criminal procedure, rulings that apply to the parties to the lawsuit but not retroactively are not merely permitted but required.289 That is, if a criminal defendant on direct review persuades a court to create a new legal rule, that new legal rule will always apply to that criminal defendant.290 But it typically will not apply retroactively to habeas petitioners who remain in the custody of the state.291 More generally, when the Supreme Court recognizes a rule of criminal procedure, it must then subsequently declare whether the rule is “new” or merely derives from an existing rule.292 For a Court that seems invested in the idea that only legislatures create new, prospective laws, this is an odd posture.293 Perhaps paradoxically, the “legislative” nature of prospective rules should serve as a signal of their value, rather than a cause for concern. In areas of law governed by statute and regulation, policymakers have long benefitted from the flexibility to create nonretroactive legal rules. Patent law has not enjoyed this flexibility, precisely because the relevant legal rules are created by judges rather than legislatures and agencies.294 Yet the federal courts do not lack the power to make purely prospective legal rules—the Supreme Court has approved the practice. The federal courts thus suffer not from a failure of authority, but from a failure of imagination. The time has come for courts to extend the practice of prospective lawmaking beyond the realm of habeas to other areas of law.295 Patent law is especially fertile ground for such an extension. Conclusion When the courts alter patent law, they upset existing reliance interests and undermine the settled expectations of patent owners. This can dissuade firms from engaging in R&D in the first place and lead to an overall decline in innovation. Perhaps more importantly, courts are aware of these concerns, which can make them reluctant to enact significant legal change. Indeed, the principle of stare decisis is based in part around the idea that courts should avoid upsetting reliance interests. Courts that fear doing violence to settled expectations can (and do) stay their hands, to the detriment of the law’s development. The solution to this problem is not for courts to refrain from updating the law. Rather, the solution is for judges to be afforded the authority to make purely prospective changes to the law, effectively grandfathering existing patents (or patent-free zones). Doing so would permit brisk legal change without fear of harming expectation-based investments. And because patents expire twenty years after filing, “old” patents that have been grandfathered would soon exit the scene. The U.S. Supreme Court has permitted prospective decisionmaking in other contexts, despite concerns for its institutional reputation. The time has come for lower courts—and the Federal Circuit in particular—to accept the Supreme Court’s invitation. Patent law and its stakeholders stand to benefit greatly from the change.

#### Biomedicine key to stop future pandemics

Weerarathna et al 23

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Biomedical science is an interdisciplinary field that includes various branches of science such as biology, chemistry, physics, and engineering. It is essential for comprehending illnesses, creating cures, and stopping pandemics from spreading. The most recent COVID-19 pandemic has brought to light the value of biomedical science in pandemic control and prevention. Biomedical scientists in the biomedical field are examining the virus's modes of airborne and surface contamination spread. The development of public health policies to stop the virus's spread is made easier with the use of this information [1]. From a biological perspective, the current processes of rapid change in natural variables produce ideal circumstances for the appearance of new and mutational existing populations of biological structures at various levels, such as bacteria, viruses, and microorganisms. The origin and spread of several infectious diseases, pandemics, and the active transmission of dangerous bacteria and viruses are all influenced by this. Such catastrophic disasters have affected humanity quite frequently during the last few centuries, killing millions of people. Diseases including smallpox, plague, cholera, typhoid, flu, tuberculosis (TB), malaria, leprosy, human immunodeficiency virus (HIV) infection, and coronary virus infection are among these catastrophes. Of the seven recorded cholera pandemics, the most recent, which spread across Asia in the 1960s, took millions of lives. Typhoid entered Europe at the start of the 19th century with the millionth sacrifice. Malaria is common in tropical and subtropical areas, encompassing both America and Asia, as well as Africa. Each year, there are up to 500 million cases of malaria reported, of which up to three million result in mortality. Around the world, eight million people contract TB each year, and two million pass away from it. About 100 million people perished from tuberculosis, influenza, and other diseases in the 20th century [2]. Using the advancements of contemporary science and technology in their various fields, including microbiology, medicine, pharmacology, and several natural sciences, it was always possible for people to find ways to prevent and effectively treat these severe infectious diseases. All of these scientific breakthroughs, however, would not have been feasible without the application of evolving techniques and tools for observing biological and technological processes. These include cutting-edge methods for observing and influencing natural processes, methods for conducting analytical research and actively influencing it, tools and techniques for processing research findings, as well as technological advancements that aid in the detection and treatment of infectious diseases that affect large populations [1]. In terms of the medical side, a scientific study to identify the most efficient ways of medical diagnosis and screening for a pandemic of this sort, established based on previously identified primary signs and symptoms characteristic of this infection, is particularly pertinent at this point. The methods of geographically distributed, remote, mobile diagnostics, which are distinctive of telemedicine diagnostic complexes and telemedicine screening systems, are also particularly effective when taking into account the characteristics of viral pandemics for rapid and active spread among the population over large areas [1].

#### Absent preparedness, future pandemics will worsen

Whiteside 24

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At the recent World Economic Forum, the World Health Organization issued a warning to world leaders, saying the world could face a pandemic 20 times worse than COVID-19 in the future. Scientists call it Disease X, a term that recognizes the next global pandemic could come as the result of an unknown pathogen rather than the spread of a currently recognized disease. Scientists with the WHO held a session last week calling on world leaders to work together to develop strategies to prevent or manage a Disease X pandemic in the future. Disease X is not real. It is the name given to a hypothetical pathogen that is being used to help plan for future health crises. Global healthcare experts on Wednesday spoke on a WEF panel called “Preparing for Disease X.” The name was coined by the World Health Organization in 2018. One of the issues raised was developing better communication strategies to reduce misinformation and conspiracy theories, even as some took to X, formerly known as Twitter, to call the session itself a conspiracy against freedom. Scientists say the most likely culprit for Disease X would be a respiratory virus, possibly one already circulating in animals that hasn’t yet made the jump to humans. Without preparedness, the WHO warned, a pandemic from Disease X could cause much more damage than COVID, which has killed more than 7 million worldwide. The WHO has already begun some initiatives to protect against a future pandemic, including efforts to support technology sharing and boost disease surveillance between countries. While Disease X was the focus of the session, it’s not the only illness that concerns epidemiologists. Other viruses that could potentially cause a pandemic include Ebola, Marburg, Crimean-Congo hemorrhagic fever, Lassa fever, SARS, MERS, Nipah virus, Rift Valley Fever, Zika virus and new evolutions of COVID-19.

## Extensions

### Links – Ex Post

#### Aff creates ex post patent reform – enforcing intellectual property rights *after* development and investment into technology, this destroys investor confidence in continued advancement

Leibowitz et al. 11

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While the open innovation model and technology transfer are important pathways to innovation, not all patent licensing and sales occur ex ante as part of a technology transfer agreement. In many cases, the licensee or purchaser already uses the patented technology when approached by the patent owner, but it lacks a license to use the technology. These patent transactions occur ex post, after the firm accused of infringement has invested in creating, developing or commercializing the technology. The firm needs the ex post license to avoid liability, even if it invented or obtained the technology independent of the patentee, because patent infringement is a strict liability offense. The ability of patentees to assert their patents against infringers is important to the patent system’s role in promoting innovation and facilitating technology transfer. The threat of a patent infringement suit deters infringement and safeguards the exclusivity that is the heart of the patent system. A business model based on invention followed by technology transfer will only succeed if a firm can prevent copying and recoup its investment in R&D. But ex post licensing to manufacturers that sell products developed or obtained independently of the patentee can distort competition in technology markets and deter innovation. The failure of the patentee and manufacturer to license ex ante with technology transfer results in duplicated R&D effort. When a manufacturer chooses technology for a product design without knowledge of a later-asserted patent, it makes that choice without important cost information, which deprives consumers of the benefits of competition in the technology market. If the manufacturer has sunk costs into using the technology, the patentee can use that investment as negotiating leverage for a higher royalty than the patented technology could have commanded ex ante, when competing with alternatives. The increased uncertainty and higher costs associated with ex post licensing can deter innovation by manufacturers. Increasing activity by patent assertion entities (PAEs) in the information technology (IT) 5 industry has amplified concerns about the effects of ex post patent transactions on innovation and competition. The business model of PAEs focuses on purchasing and asserting patents against manufacturers already using the technology, rather than developing and transferring technology. Some argue that PAEs encourage innovation by compensating inventors, but this argument ignores the fact that invention is only the first step in a long process of innovation. Even if PAEs arguably encourage invention, they can deter innovation by raising costs and risks without making a technological contribution. The clear benefits for innovation and competition stemming from ex ante patent transactions contrast with the detrimental and ambiguous effects of ex post transactions. An important goal in aligning the patent system and competition policy is to facilitate ex ante transactions while making ex post transactions less necessary or frequent. Improving the notice function of patents would help with both. Manufacturers often license ex post because they were not aware of the patent ex ante. Multiple factors can contribute to notice failure, including overbroad, vague claims, the large number of patents potentially relevant to IT products, and the pendency of patent applications in the Patent and Trademark Office (PTO). More clearly defined patent rights could help companies better find and license technology they wish to develop ex ante, which would support technology transfer. Better notice could also help companies obtain licenses or design around patents in advance of marketing a product, thereby decreasing the amount of ex post licensing. Remedies law requires a careful balance to accomplish the goal of facilitating ex ante transactions while reducing the frequency of ex post transactions. On the one hand, any adjustments to remedies law must be careful not to undermine the patent system’s incentives to innovate. On the other hand, if remedies overcompensate patent owners compared to the market reward absent infringement, they can distort competition and encourage patent speculation. Improvements in both notice and remedies law, as discussed in the following sections, can better align the patent system with competition policy and balance these concerns.

#### The affirmative creates a massive increase in ex post patent claiming – disincentivizing innovation and technological creation

Chiang 05

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Although individual methods ex post claiming have been analyzed,11 the ex post facto nature of claiming itself has generally escaped scrutiny. The analysis for disparate methods of ex post claiming, however, shares many common traits. Ex post claiming methods are commonly defended on the grounds that patentees do not fully appreciate the nature of their invention until later insights arise,12 and that patentees will inevitably make claim drafting mistakes that can be exploited by competitors.13 Contrary to the practice’s defenders, these represent the precise problems with ex post claiming, not its redemption. First, permitting patentees to cover later insights is equivalent to permitting patentees to obtain monopoly rights over something they did not actually invent, either by covering new competitor products or avoiding newly discovered prior art. This results in a windfall gain to the patentee. Because the windfall gain is unexpected at the time of filing, there is relatively little increase in the incentive to innovate given the risk discounting that must be applied. Second, even when ex post claiming is not used to cover later innovations, and instead used only to correct good faith mistakes in articulating the actual invention at the time of filing, the availability of ex post claiming inefficiently shifts the risk of claim drafting mistakes from patentees to competitors. 14 Because patentees thus benefit from their own mistakes, they have no incentive to avoid them; instead, competitors who bear the risk must take preventative measures to avoid the risk. Obviously, a patentee can be expected to know his own invention and avoid claim drafting mistakes at relatively low cost; while competitors can only discern claim drafting mistakes by the patentee at great cost, if such avoidance is even feasible. Placing the risk of drafting mistakes and the onus of avoiding them on competitors is a misguided allocation of the risk that increases the transaction costs of the patent system. The problems created by ex post claiming are plain. However, there is an important countervailing consideration: not all claim drafting mistakes are avoidable at low cost, and not all competitors will suffer harm from those mistakes.15 Society would not benefit if patentees spent millions of dollars in attorneys fees to avoid a claim drafting mistake when the mistake causes competitors only hundreds of dollars in losses. Over-punishing injurers (whether a tortious driver or a bad claim drafter) can be as problematic as under-punishing. A complete prohibition on claim modification could lead to devoting excessive amounts of time and money on avoiding claim drafting mistakes and confer windfall gains upon accused infringers. If competitors never see the mistake-infected patent, they cannot be deceived by the mistake, and the mistake thus causes no harm. Allowing ex post claim changing to remedy harmless mistakes is efficient, because it prevents patentees from devoting excessive resources to ex ante claim drafting.

### Links – Traditional Knowledge

### Links – Strengthening Corporate Patents

#### Strengthening patents results in worsened patent litigation, damaging competition and innovation

Brough 24

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Patent eligibility, or the fundamental question of what is patentable, is currently under congressional review. Sens. Thom Tillis (R-N.C.) and Chris Coons (D-Del.) have introduced the Patent Eligibility Reform Act (PERA) to reform Section 101 of the U.S. Patent Act, which defines what can be patented. But some of the proposed changes do much more than clarify patent eligibility, aiming instead to reverse a series of Supreme Court decisions issued in response to growing concerns over patent abuse and its chilling effects on innovation. More importantly, while the Supreme Court has consistently held that “laws of nature, natural phenomena, and abstract ideas” are not patentable, these legislative proposals attempt to upend that position and expand the scope of patent eligibility directly contra to court rulings. Enhancing Innovation or Creating Monopolies? In many ways, recently proposed changes would return the patent system to policies of the late 1990s and early 2000s, when the courts were beset with patent litigation originating from excessive claims of patentability. Allowing companies to patent abstract business methods or practices prompted a surge in lawsuits targeting other companies using similar business processes—even obvious or commonsense practices. While broader patent eligibility strengthens the hand of patent owners, the impact on innovation is less clear. Research has found that such overly broad patents generate excessive litigation while creating significant barriers to entry that limit competition. This ultimately sparked the Supreme Court rulings that established new limits on the possibility of patenting abstract concepts or inventions. The Patent Eligibility Reform Act Given the longstanding tension between innovation and monopolization, any legislative changes to patent policy must be evaluated carefully. The bill currently under consideration in the U.S. Senate proposes three key changes: Overriding recent court decisions: The bill seeks to revisit important Supreme Court decisions including Alice Corp. v. CLS Bank International (2014), Association for Medical Pathology v. Myriad Genetics (2013),and Mayo Collaborative Services v. Prometheus Laboratories, Inc. (2012). These decisions narrowed the scope of patent-eligible subject matter by declaring naturally occurring gene sequences ineligible. The PERA would make it easier for patents to be issued for inventions that may be ineligible under existing law for being too abstract or for incorporating natural phenomena. Providing new guidelines: The PERA would also expand patent eligibility by eliminating existing judicial exceptions to patentability and replacing them with a narrow list of inventions that cannot be patented. These new exceptions include: A mathematical formula that is not part of a claimed invention; A process that is substantially economic, financial, business, social, cultural, or artistic, unless it cannot be performed without a machine or manufacture; A process that occurs in the mind or in nature, wholly independent of human activity; An unmodified gene, as it exists in the human body; and An unmodified natural material, as it exists in nature. While one of the PERA’s goals is to provide greater certainty with respect to patent eligibility, these exceptions are sure to pose legal questions. What, for example, is a process that is substantially economic, or business, or cultural that cannot be performed without a machine? Expanding patent eligibility: Importantly, the legislation states that claimed patents in areas like biotechnology, diagnostic testing, and artificial intelligence (AI) are eligible if they are incorporated into a “useful process, machine, manufacture, or composition of matter, or any useful improvement thereof.” Supporters seek to clarify that inventions involving natural phenomena, laws of nature, and abstract ideas are only eligible for patent protection if they are practically applied or integrated into a practical application. Expanding Patent Eligibility Limits Innovation and Competition Supporters claim that patent eligibility practices in the wake of the aforementioned Supreme Court decisions hinder innovation and investment in critical technologies like AI, personalized medicine, and diagnostic testing. On the other hand, critics assert that the PERA would restore an earlier patent regime that granted patent protections too broadly, making it difficult for true innovators to navigate complex and far-reaching patents that limit entry into the market. “Patent thickets” became prevalent in the late 1990s and early 2000s, particularly among pharmaceutical companies seeking to extend their exclusivity over blockbuster drugs in order to keep generic competitors at bay. This term refers to the practice of creating impenetrable walls of patents on different aspects of the same drug—from the primary patent covering the compound itself to secondary patents on characteristics like method of use, formulation, and other aspects of drug delivery—thereby creating a dense web, or “thicket,” of patents surrounding a single product. For example, I-MAK found that America’s top 10 best-selling drugs possess an average of 74 granted patents. These patent thickets extend the monopoly protection enjoyed by drug manufacturers well beyond the original patent while keeping low-cost generics out of the market. Another tactic for extending monopoly protection of brand-name drugs is “evergreening,” or adding new patents to a drug as existing ones expire. By pursuing patents on different aspects of a drug, such as packaging, dosage, or other properties, it is possible to extend its dominance in the marketplace. While some changes may be warranted, others may simply protect exclusivity. This makes it important to evaluate a patent’s validity—something proposed changes within the PERA would make more difficult. “Product hopping” is yet another way to game the patent system. Here, a company produces a reformulated version of a drug—by changing the dosage or introducing an extended-release version, for instance—and markets the new product heavily while urging prescribers to switch. They may even take the old product off the market. In one example, as the patent on its popular anti-ulcer drug Prilosec expired, AstraZeneca switched to Nexium, a drug with minimal modifications and an additional 13-year patent life. This product hop was estimated to cost the U.S. health care system over $2 billion annually. Expanding patent eligibility to allow companies to obtain patents on abstract ideas, natural phenomena, or even basic computing functions would significantly extend the monopolies of patent owners, stifling innovation and competition by giving patent holders greater authority to challenge new entrants for infringement as they try to access the market. It would abuse the tools of government to slow down competition and stifle innovation.

### Internal Links

#### Private investment key to medical innovation

Maloney 24

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Patients nationwide suffer from nearly 7,000 rare diseases, yet only 5 percent of those have an available treatment. That is because it takes 10-15 years on average and more than $2.6 billion to develop and bring a new medicine to market. Only 12 percent of the molecules that enter clinical trials ever receive Food and Drug Administration approval. Private equity is also financing promising drug candidates that need time and funding to get into patients’ hands. These investments have enabled the development of treatments for several life-threatening conditions, such as Leukemia, Alzheimer’s, heart disease, HIV, and breast cancer, and for several debilitating conditions, including rheumatoid arthritis, diabetes, and ulcerative colitis. Late last year, Massachusetts-based Anthos Therapeutics announced their new drug demonstrated a potential to significantly reduce the risk of blood clots, providing a safer alternative for the 12.1 million Americans expected to suffer from atrial fibrillation by 2030. The drug, abelacimab, cut the overall risk of bleeding by 67 percent when compared to the current standard of care used by patients. The Food and Drug Administration has said it would fast-track its review of the treatment after overwhelming success in the latest round of testing.

## Aff Answers

### Uniqueness

#### Non-unique: investment is down in biomedicine – patents without clinical data fail to inspire investment

Wu 24

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The number and amount of biotechnology financings dipped in 2023, with venture firms investing 25% fewer dollars in companies compared to the year prior, according to new quarterly data released Thursday from Pitchbook and the National Venture Capital Association. Venture capital firms are increasingly investing in later-stage drug companies, which accounted for about 40% of deals in 2023. Rather than invest heavily in preclinical work, VCs now appear to be waiting for drug developers to enter or have a road map to clinical trials, said Kazi Helal, Pitchbook’s senior healthcare analyst. Pitchbook and NVCA also found venture activity dropped across all sectors last year, to $170.6 billion from $242.2 billion in 2022. Veteran biotech VCs like Westlake Village BioPartners, OrbiMed and, most recently, Venrock have reloaded with new funds, while new life sciences-focused investors such as Yosemite and Cure Ventures launched last year. But for how flush with new funding VCs have become, they haven’t been deploying as much into new companies. Within the biopharma sector, venture firms invested $18.4 billion across 481 deals last year, according to the report. That was down from 2022’s total of $24.5 billion over 559 deals and matches a trend of venture firms opting for fewer but larger deals. In their quarterly report on dealmaking and venture capital investment, Pitchbook and NVCA also counted fewer cell therapy deals compared to other modalities, with the bulk of capital — about $14.2 billion — going to small molecule and biologics development. Over the last two years, many publicly traded genetic medicine developers, including Editas Medicine, Intellia Therapeutics and Beam Therapeutics, have seen declining share value and turned to layoffs. A combination of trial hurdles and questions on the pricing have weighed down investor enthusiasm, Helal said. “A lot of these early bets are still maturing,” Helal said. With more weight being put on trial data, early-stage startups have had a harder time raising money. And for those looking to go public, the bar appears to be staying higher than in 2020 and 2021. “You can’t have a machine learning, generative AI [company] and IPO without any clinical data,” Helal said. “The data demand is pretty high. You can’t just have 10 partnerships putting in $50 million each, you need to actually have your internal pipeline.” Nor is it enough to rely on the popularity of certain classes of medicine, such as GLP-1 drugs for obesity, to drive investor interest. “We’re at an early-stage saturation point” with companies chasing those metabolic diseases, Helal said.

### Links – Traditional Knowledge

#### Turn: IP protection of TK avoids the loss of TK through misappropriation and encourages better use – Squo policy is worse by destroying biodiversity essential to TK

Brody 10

Baruch A. Brody was an American bioethicist. He was the Leon Jaworski Professor of biomedical ethics and former Director of the Center for Ethics, Medicine and Public Issues at The Baylor College of Medicine and Andrew Mellow professor of Humanities in the Department of Philosophy at Rice University. "Traditional Knowledge and Intellectual Property." Published by the Kennedy Institute of Ethics Journal, vol. 20(3). p. 8. Published in September 2010. Available here: (https://www.researchgate.net/publication/49659959\_Traditional\_Knowledge\_and\_Intellectual\_Property#pf8) - AP

The promotion of the use of TK is an important objective in itself. Article 8 (j) of the CBD, often quoted in relation to the protection of TK, requires the promotion of the “wider application” of TK. It may be argued that protecting TK against loss and misappropriation, or ensuring compensation to TK holders, are necessary elements to stimulate the broader use of such knowledge. Protection may be, in this context, a tool for facilitating access to TK 25. Some form of protection may create the basis of trust required for the local/indigenous communities to part with their knowledge, and improve their position to obtain value from it 26. If some rights were recognised, knowledge holders may be more prepared to provide access to their knowledge and, if fairly compensated, they will have more incentives to conserve it and ensure future access. However, the recognition or establishment of new types of IPRs on TK may reduce, rather than promote, the use of such knowledge. In dealing with TK, policy makers need to balance very carefully the expected benefits from a possible IPRs-like protection of TK, with the costs that are likely to arise from the limitations on its use. This may be particularly important in the case of TM, since an IPRs-like protection may reduce the access to products and treatment that are essential for a large part of the developing countries’ population, particularly the poor. In the case of farmers’ varieties, IPRs protection may also reduce the exchange of materials and the biodiversity created on-farm27. The impact on genetic diversity of modern breeding promoted by IPRs in the Netherlands has been a “narrowing circle of genetic diversity”, characterised by the replacement of landraces by breeder’s varieties developed for high input/high production agriculture, and by the narrowing down of the gene pool used to breed new varieties28.Thus, rather than “protecting” TK in a way that limits access to it, governments may aim to promote the use of TK, complimenting this with measures to prevent misappropriation. An example of this approach is provided by Act No. 8423 (1997) of the Philippines, which aims “to accelerate the development of traditional and alternative health care” by improving the manufacture, quality control and marketing of traditional health care materials29. Promoting development may also be a fundamental motivation behind protecting TK from destruction and loss. TK is an underutilised resource in the developmentprocess30. Legal protection may help to exploit the opportunities of TK-based products and services31. TK may also be a critical resource for strengthening local innovation, and innovation is important for reinforcing (even rebuilding) local cultures 32.

### Links – Strengthening Corporate Patents

#### Turn: Strengthening patents improve innovation through funding and improved research resources

Heus et al. 17

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The prime reason that should motivate researchers to be engaged in the development of IPR is that it is very rewarding to see a technology, originating from their own lab, developed into a final product that ultimately benefits patients.

Secondary to this, there is the potential for financial income, both for their research group and for them personally, even though the chance of substantial revenues accruing from any given patent application is typically low. Generally speaking, only a small minority of patented inventions will generate a significant return, and even then the amounts concerned are small in comparison to the institute’s total R&D budget. There are however good opportunities for funding of invention-related research, as alluded to in section 1. With respect to personal remuneration, the majority of research institutes has IP guidelines that allow individual inventors to receive a certain share of the revenues received by the institution. This income is generally being obtained through licensing of patents to a commercial entity or through the sale of shares held by the institute and/or the inventor in the spin-off company in which the invention is further developed.

A third advantage for academics that are actively involved in developing IP, is that such activities are becoming increasingly better appreciated by research institutions and are often used as a criterion to rate academics when promotions or tenure positions are to be decided upon.

Not only translational or clinical researchers may think of getting engaged in the development of IP. The example of the invention of the polymerase chain reaction shows that also fundamental researchers should keep an open eye to what possible exploitable inventions may come forth from their projects.